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# **A hip wear simulator with 100 test stations**

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## ABSTRACT

A novel high-capacity hip wear simulator of the pin-on-disk type was designed, built and validated. This so-called Super-CTPOD (circularly translating pin-on-disk) device has as many as 100 separate test stations, being an advanced version of the previously validated 12-station CTPOD. A validity test was done so that in all stations, the specimens and the test conditions were as similar as possible. Hence for the first time in this field, an adequate number of similar tests was done for a proper statistical analysis of wear data. The pins were conventional, gamma-sterilized ultra-high molecular weight polyethylene, and the disks were polished CoCr. The lubricant was diluted calf serum, and the test length 3 million cycles. In the course of the test, the pins became highly polished, whereas the disks remained practically unchanged. The majority of the polyethylene wear particles were rounded with a mean diameter of 0.25  $\mu\text{m}$ . The 100 wear factor values computed from the 100 steady-state wear rate values of the pins were normally distributed, the mean  $\pm$  95 % confidence interval being  $1.63 \pm 0.017 \times 10^{-6} \text{ mm}^3/\text{N m}$ . The standard deviation was 5.4 % of the mean. There were no outliers. The wear mechanisms and the wear factor agreed well with clinical findings. Altogether, the Super-CTPOD test system was shown to be a unique combination of validity, low variation, capacity, efficiency, reliability, productivity, economy, ease of operation, and compact size.

*Keywords:* hip wear simulation, ultra-high molecular weight polyethylene, wear data statistics, wear test validation, high-capacity wear test

## INTRODUCTION

It is characteristic of wear tests that the results show a considerable variation, wear testing of orthopaedic biomaterials being no exception. The variation is basically due to the fact that there are numerous factors affecting the wear mechanisms, and the phenomena lying behind the tribological behaviour of surfaces are complex. Some of the important variables, such as the degradation of the serum-based lubricant with time, are still poorly understood and difficult to control. It is therefore most desirable to run a large number of similar tests for the statistical analysis of test data, and for the comparison of differences in means between materials, test conditions, etc. Most of the existing wear test devices for prosthetic joints and their materials are very expensive and have 12 test stations at the most. Since there are not too many of such devices even worldwide, and since one test takes at least 6–8 weeks to run, it can be stated that the scarcity of valid wear testing capacity has been a true bottleneck in the evolution of orthopaedic biomaterials.

In 1996, the present author designed and built a 12-station circularly translating pin-on-disk (CTPOD) device that was shown to produce wear highly similar to that occurring in total hip prostheses in vivo, being the first truly simple design to reach this goal [1]. Hence, the CTPOD is called a hip wear simulator, in distinction from hip joint simulators that are used for wear testing of actual hip prostheses. The crucial factor was found to be the type of relative motion. In the circularly translating motion, the direction of sliding changes continually, as is the case in the hip joint in walking. This type of sliding together with a serum-based lubricant results in adhesive wear manifested as a polished appearance of the polyethylene wear surface, and a production of polyethylene wear particles mostly in the 0.1–1  $\mu\text{m}$  size range. These observations are in good agreement with clinical ones [2–4]. Moreover, the wear factor values produced by the CTPOD for conventional ultra-high molecular weight polyethylene sliding against a polished CoCr counterface range from 1 to 2

$\times 10^{-6} \text{ mm}^3/\text{N m}$ , being close to those measured for retrieved conventional metal/polyethylene total hip prostheses [5]. All this is true despite the fact that the CTPOD test employs a flat-on-flat contact instead of a ball-in-socket contact of the actual prosthetic hip. Interestingly, the CTPOD motion is analogous to that of the most widely used hip joint simulator, the biaxial rocking motion design, originally introduced by McKellop and Clarke [6]. The type of loading was found to be clearly less important than the type of motion [7].

In the present paper, the second generation of the CTPOD design is introduced. This so-called Super-CTPOD has 100 separate test stations to make possible, for the first time, samples of sufficient size for a proper statistical analysis. The capacity of 100 stations is unparalleled (Table 1). Despite the fact that the number of stations is so high and the specimens are *not* miniaturized, the device is of very compact size,  $384 \text{ mm} \times 339 \text{ mm} \times 333 \text{ mm}$  ( $w \times d \times h$ ). With the set of special tools, the assembly and disassembly of the specimens is extremely quick and easy, although the test chambers are packed in the minimum of space. The motion, load and specimen size are identical to those of the 12-station CTPOD. A new feature is the temperature control system, which keeps the lubricant temperature uniform within one degree Celsius in all 100 stations. The volume of the lubricant in each test chamber is 16 ml, 33 % higher than that in the 12-station CTPOD, to reduce the risk of excessive protein precipitation, which could compromise the validity of the wear simulation. The only lacking feature of the Super-CTPOD compared with the 12-station CTPOD is the friction measurement, which was dictated by space limitations.

To see whether the device produces valid wear results with reasonable variation, conventional gamma-sterilized polyethylene pins were tested against polished CoCr disks so that the specimens and the test conditions in all 100 stations were as similar as possible. This material combination was chosen because it is the most commonly used combination in prosthetic joints, and there are plenty of scientific publications on its tribological behaviour.

## MATERIALS AND METHODS

The Super-CTPOD design (Fig. 1) consists of three main modules, loading, motion, and pin guiding (Fig. 2). The loading and pin guiding modules can be easily demounted, after which the specimens (Fig. 3) can be disassembled with special tools (Fig. 4) for cleaning, examination and wear measurement. The loading module is a rigid aluminum box that weighs 21 kg and contains 100 individual pneumatic actuators. The maximum operating pressure of the actuator is 0.1 MPa, which generates a load of 165 N.

The motion module consists of a base plate, a motion plate, and the circular translation motion mechanism between them. The motion plate makes the electromechanically driven circular translation in the horizontal plane. The motion plate is made of stainless steel. Both of its sides are machined and ground. In addition, the upper side is polished and diamond coated. The motion plate is surrounded by a brim forming a basin for the temperature control system. The basin contains water circulated by a pump through a heat exchanger. With the heat exchanger working by tap water run by a thermostat valve, the water temperature within the basin can be accurately controlled. There are 100 separate, similar test chambers. The test disk forms the bottom of the test chamber, and a piece of PVC tube forms the brim with a height of 35 mm and internal diameter of 28 mm (Fig. 3). The brim is fixed to the disk with a silicone o-ring. The chambers are placed on the motion plate, locked horizontally by two guide pins per disk, and surrounded by the water bath. The o-ring prevents the mixing of the lubricant and the circulating water. It was found in the system tests that the lubricant temperature was one degree above the water temperature. For instance, if the incoming and outgoing water temperatures were 18.5 °C and 19.5 °C, respectively, the serum temperatures were between 19.5 °C and 20.5 °C. The direction of circulation was regularly changed to further reduce the temperature differences between the chambers. The chambers are organized in 11 rows so that the number of chambers in the rows are 7, 8, 9, 10, 11, 10, 11, 10, 9, 8, and 7. The rows are of

unequal width in order to leave space for the pillars in the corners (Fig. 2). In this way, the dimensions of the device were minimized. The pillars carry the load and the frictional force. The drive motor and the temperature control system are located beneath the installation table shown in Figs. 1 and 2.

The pin guiding module, with a total weight of 15 kg, is a thick polyacetal block having 100 precision-made bores for stainless steel precision shafts, the rotation of which is prevented by levers. A polyacetal sleeve is pressed around the lower end of the shaft, and the test pin is pressed into the lower end of the sleeve (Fig. 3). By using this press-fit principle, the radial dimension of the pin holder is minimized. The pin holder must be thin enough so that there is enough space within the lubricant chamber with an internal dia. of only 28 mm, considering the motion along a circular track of 10 mm dia. The advantages of the high shape of the chamber are that the mixing of the lubricant by the pin holder is efficient preventing sedimentation, and the surface area of the lubricant relative to its volume is small retarding evaporation. The pneumatic actuator pushes the shaft downwards from its upper end. Since the shaft has only one degree of freedom, vertical translation, the contact force between the pin and the disk is equal to the force generated by the pneumatic actuator. This is assisted by two factors: (1) there is a small clearance between the shaft and the bore, and (2) the frictional force with a continual change of direction tends to ‘whirl’ the shaft within the bore facilitating its axial movement downwards, as the pin shortens due to wear.

The motion was such that the pin translated, without rotation, along a circular track of 10 mm diameter on the disk. Therefore, the direction of sliding relative to the pin changed continually. One complete revolution of the direction of sliding, which took 1.0 s, is called a cycle. The sliding speed was constant, 31.4 mm/s. The diameter of the cylindrical polyethylene pin was 9.0 mm and height 12.0 mm. The wear end of the pin was flat and non-chamfered. The CoCr disk had a diameter of 28 mm and thickness of 10 mm. The contact was

flat-on-flat. The load was static 70.7 N, and nominal contact pressure therefore 1.1 MPa.

The pins and the disks were supplied by Centerpulse Orthopedics, a Zimmer Company. The pins were made from conventional, calciumstearat-free ultra-high molecular weight polyethylene GUR 1020, 'Sulene-PE', ISO 5834-1/-2. After the machining from a compression molded sheet, the pins were gamma-irradiated by 25–40 kGy in nitrogen. The disks were made from CoCrMo wrought alloy 'Protasul-20', ISO 5832-12. The wear faces of the disks were machined, ground, and finally diamond-polished to an arithmetical mean surface roughness value of 0.01–0.02  $\mu\text{m } R_a$ . The surface roughness was measured with a Taylor Hobson Surtronic 3+ diamond stylus instrument using 0.8 mm cut-off and 4 mm evaluation length.

The lubricant was prepared so that triple 0.1  $\mu\text{m}$  sterile filtered HyClone Alpha Calf Fraction serum, catalog no. SH30076.03, lot no. AFL5848, was diluted 1:1 with Milli-Q-grade distilled water. Hence, the protein content of the lubricant was 21 mg/ml. No additives were used. Each chamber contained 16 ml of lubricant. The lubricant temperature during the test was maintained at 20 °C (range 19.5–20.5 °C).

The amount of wear was measured by stopping the test and weighing the pins at intervals of half a million cycles using a procedure published elsewhere [13]. During a weighing stop, the specimens, pin holders, lubricant chambers and o-rings were carefully cleaned. The pins were first vacuum desiccated for 30 min and then allowed to stabilize for 2 hours in the room atmosphere before the weighing, which was done with a Mettler AT261 DeltaRange balance to a repeatability of  $\pm 0.03$  mg. The original mean weight of the pins was 717.11 mg (range 712.98–719.64 mg). After the weighing, the specimens were reassembled, and the test was continued with fresh lubricant. The total length of the tests was 3 million cycles. The steady-state wear rate, in mg per one million cycles, was taken to be the slope of the linear regression line in the diagram weight loss versus number of cycles. The first half a million cycle was



omitted in the linear regression because it is a transient phase dominated by the removal of the original machining marks. Taking into account the density of polyethylene, the load, and the sliding distance per cycle, the wear factor  $k$  was calculated so that the wear rate was divided by  $(10^6 \times 0.94 \text{ mg/mm}^3 \times 70.7 \text{ N} \times 0.0314 \text{ m})$ . The wear factor is a useful quantity because it makes possible the comparisons with in vitro and in vivo wear measurements for actual hip prostheses. All the 100 tests were run simultaneously.

Polyethylene wear particles were isolated from samples of used serum lubricant by NaOH digestion, HCl neutralization, and filtration on 0.05  $\mu\text{m}$  pore size polycarbonate filters, and examined with scanning electron microscopy (SEM) and image analysis tools as described elsewhere [14].

## RESULTS

In visual examination, all pins were highly polished (Fig. 5). Microscopy revealed a featureless, flat topography in every pin (Fig. 6a) with some mild criss-cross scratches (Fig. 6b). The disks were not damaged, and no patches or layers formed on them during the tests. Only seldom some subtle, circular scratches were observed. The occurrence of these rare, barely visible scratches did not correlate with the wear rate of the corresponding pins. The SEM of the polycarbonate filters revealed that the overwhelming majority of the wear particles (Fig. 7) were rounded and their mean equivalent circle diameter (ECD)  $\pm$  SD was  $0.25 \pm 0.10 \mu\text{m}$  ( $n = 125$ ). Agglomerations, from which individual particles could not be distinguished with certainty, were common.

The dependence of wear on the number of cycles was highly linear, the correlation coefficient  $R^2$  of the linear regression of the mean weight loss values being 0.9982, the slope of the regression line 3.40 mg per one million cycles, and the y-axis intercept 0.70 mg (Fig. 8). The mean  $k$  value computed from the slope was  $1.63 \times 10^{-6} \text{ mm}^3/\text{N m}$ . The same value was naturally obtained by performing the linear regression analysis for each pin, and computing the mean of the 100 values. The correlation coefficient  $R^2$  of the linear regression analysis of the gravimetric wear of individual pins ranged from 0.9906 to 0.9998 with a mean of 0.9973. The 100  $k$  values, computed from the 100 steady-state wear rate values, were normally distributed (Table 2, Figs. 9 and 10). There were no outliers. Normality tests (Shapiro-Wilk  $W$ , Anderson-Darling, Martinez-Iglewicz, Kolmogorov-Smirnov, D'Agostino skewness, D'Agostino kurtosis, and D'Agostino omnibus) could not reject normality at 5 % significance level. In a normal distribution, 68.3 % of the observed values lie within  $\pm 1$  SD of the mean. In the present test, 71 of 100  $k$  values lay within the mean  $\pm 1$  SD, i.e., between  $1.54$  and  $1.71 \times 10^{-6} \text{ mm}^3/\text{N m}$ .

## DISCUSSION

A novel pin-on-disk hip wear simulator, the Super-CTPOD, was introduced. The most useful and valuable characteristics of the device, validity, low variation, capacity, efficiency, reliability, productivity, economy, ease of operation, and compact size, are discussed below.

Validity is the most important characteristic of a wear simulator. In the present case, the validity is judged by the similarity of the wear produced by the simulator to that occurring in prosthetic hip joints in vivo. The crucial results, the polished appearance of the worn polyethylene surface, the undamaged counterface, the size and shape of the wear particles, and the mean wear factor value agreed well with clinical findings [2–5]. In the absence of severe femoral head damage, the main load bearing zone of retrieved polyethylene acetabular cups typically appears polished, indicating adhesion as the principal wear mechanism [2,3]. The majority of wear particles isolated from periprosthetic tissues are rounded and range in diameter from 0.1  $\mu\text{m}$  to 1  $\mu\text{m}$  with a mean of 0.5–0.7  $\mu\text{m}$  [3,4]. In the present study, the mean ECD of wear particles was somewhat smaller, 0.25  $\mu\text{m}$ , which may be at least partly due to the fact that the filter pore size used was 0.05  $\mu\text{m}$ , whereas 0.2  $\mu\text{m}$  pore size is the most widely used, and used also in the two studies of clinical particles [3,4]. It has been found that the filter pore size has a significant effect on the observed size distributions of the particles [15]. It is recommended that 0.05  $\mu\text{m}$  pore size is used instead of 0.2  $\mu\text{m}$ , because a significant proportion of particles are below 0.2  $\mu\text{m}$  in diameter. The mean clinical wear factor measured for 129 retrieved Charnley polyethylene acetabular cups worn against 22 mm dia. stainless steel heads with varying abrasive damage was found to be  $2.1 \times 10^{-6} \text{ mm}^3/\text{N m}$  [5]. In the present study, there was practically no damage on the disks, which may partly explain the slightly smaller mean wear factor of  $1.63 \times 10^{-6} \text{ mm}^3/\text{N m}$ . Retrieved heads made of CoCr, that is harder than stainless steel, typically have retained their original mirror finish showing only occasional scratches [3]. When scratching occurs, it is often caused by abrasive

acrylic particles, both in the cases of stainless steel [5] and CoCr heads [16]. In the present wear simulation, acrylic particles and all other possible contaminants were deliberately left out, because first a valid, clean wear test that will serve as a reference test for any future study, needed to be done. A scratched counterface has been shown to produce more large, elongated polyethylene particles [13]. The oxidation of polyethylene is another important issue, as it may seriously impair the wear resistance in vivo [17]. The majority of laboratory wear tests have been done with non-aged material, as in the present study.

Low variation of the results indicated that the test method was of high quality. Achieving a 95 % confidence interval of the mean as small as that in the present study,  $1.63 \pm 0.017 \times 10^{-6} \text{ mm}^3/\text{N m}$ , is very difficult with low  $n$  values, because the length of the interval is proportional to  $1/\sqrt{n}$ . For the first time in this field, it was shown that  $k$  is normally distributed. The comparison of the means of two samples using the  $t$  test requires that the data are normally distributed. Consider a theoretical example: the wear properties of two types of polyethylene, A and B, are compared with the Super-CTPOD. The mean  $k$  of type A is found to be  $1.63 \times 10^{-6} \text{ mm}^3/\text{N m}$ , and the mean  $k$  of type B is found to be 10 % higher than that of type A, a difference not too dramatic, but with potential clinical significance. It is assumed that their wear factors are normally distributed with SDs equal to that of Sulene-PE,  $0.088 \times 10^{-6} \text{ mm}^3/\text{N m}$ . It is easy to calculate using the  $T_{2n-2}$  distribution that the lowest value of  $n$  resulting in a 95 % confidence that type B really wears faster than type A is 4. This would leave abundance of machine capacity for other materials to be run simultaneously. With new materials, the sample size must of course be decided before anything is known about the distributions, but this example gives an idea of the differentiation power of the Super-CTPOD. Note that in the present study, (a) the run was successful at the first attempt, (b) all the 100 tests were run simultaneously, (c) there was not a single outlier pin with exceptionally low or high  $k$  value (Fig. 10, all values are between the 95 % confidence limits), (d) none of

the results was rejected, and (e) there were no reruns. Moreover, the appearances of all 100 pins, and of all 100 disks were highly uniform.

Capacity of 100 separate test stations is superior to all previous devices (Table 1). The high capacity is perhaps the single most original feature of the Super-CTPOD. Wear testing of orthopaedic biomaterials is inevitably time-consuming. For a thorough evaluation of, e.g., the effect of different sterilization methods, different types of lubricants, or different types of counterface on the wear behaviour of a certain material, or for a comparison of the wear behaviour of a large number of different materials, the capacity is of the utmost importance. Typically, existing wear simulators and joint simulators units have 12 test stations at most making it impossible to implement large test programmes within a reasonable time scale. If miniature specimens were used, it would not be too difficult to pack even a much higher number of test stations than 100 into one CTPOD device, but it has been shown that the wear behaviour of a miniaturized contact surface is quite different from that of actual bearing surfaces *in vivo* [18]. Note that the Super-CTPOD specimens are not miniaturized. On the contrary, 9.0 mm is a relatively large pin diameter. Moreover, the wear face diameter can easily be increased up to 12.5 mm, the o.d. of the pin holder sleeve.

Efficiency is, however, more than sheer capacity. The downtime for wear measurement, including disassembly, cleaning, weighing, and reassembly must be as short as possible so that the entire test can be performed in a minimum of time. In Super-CTPOD testing, the downtime proved to be only c. 12 hours with one operator (V.S.). With 1 Hz test frequency, a three million cycle test for 100 specimens with six periodic wear measurements can therefore be completed in just 38 days, as in the present study. No doubt, this is a mark of efficiency.

Reliability, as an absence of technical malfunction, proved to be as good as it can possibly be, since the test needed not be stopped even once during the six 500 000 cycle test stages. Essential for reliability is that the structure of the simulator is sound and robust from

the machine design point of view, all principles, functions, mechanisms, components, machine elements, and parts being optimized, and as simple as possible in relation to the objective, valid hip wear simulation with low variation.

Productivity naturally is a result of the high capacity, efficiency, and reliability of the Super-CTPOD test system. Now it is possible, for the first time, to ‘mass-produce’ valid wear data without any additional effort compared with existing low-capacity simulators. Moreover, the Super-CTPOD design itself is ideal for serial manufacture. A set of, say, ten units with a massive total capacity of 1 000 test stations would be a truly powerful hardware in ambitious biotribology research programmes.

Economy of the Super-CTPOD is based on its sound design consisting of simple parts made from common materials, and of industrial components (pneumatics, bearings, electrical drive). The shapes of the specimens are also simple, making them economical (Fig. 3). The pin is a simple cylinder, and the only special features in the disk are the groove for the o-ring, a recess for the o-ring removal tool, and two 3 mm bores on the lower side for the locking pins of the motion plate. No screws are needed in their fixation. In the present study, the grinding and polishing of the disks were done manually at HUT, but the shape of the disk lends itself very well for modern, automatic polishing machines.

Ease of operation is important from the point of view of efficiency, and special attention was paid to this aspect in the design of the device. The Super-CTPOD was the tenth wear test device designed, built, and operated by the present author, and so the importance of this aspect was very clear from personal experience. For instance, all the parts that need to be cleaned (the specimens, pin holders, lubricant chambers and o-rings), are easily cleaned as batches in an ultrasonic cleaner. During the running, no measures by the operator are needed apart from normal supervision.

Compact size, 384 mm × 339 mm × 333 mm (w × d × h, above the installation table

shown in Figs. 1 and 2), makes it easy to move the device, and locate it, e.g., in a clean air chamber, if desired. The compact size makes the device and its modules light, but does not cause any inconvenience for the operator thanks to the set of assembly and disassembly tools for specimen handling (Fig. 4).

As the temperature was maintained at 20 °C, the evaporation from the open lubricant chambers was so minimal that the device needed not be stopped for the addition of water during the 139 hour periods that each 500 000 cycles took to run. The fact that the results were so similar to clinical findings proves that the lubricant temperature need not be kept at 37 °C. The lower temperature has the advantage that the microbial growth and the denaturation of the proteins is slower. Hence, the wear mechanisms remain more stable. It is known that the protein precipitation, which increases with increasing temperature, can erroneously change the wear mechanisms in a wear test so that precipitated protein slurry acts as an anti-wear agent [19], which does not happen in vivo. Due to the microbial growth, the use of the 37 °C temperature necessitates the use of antibiotics, such as sodium azide, that are not only toxic, but also may affect the wear mechanisms. The present study showed that there is no need to use any additives whatsoever in the serum, if the temperature is kept at 20 °C, not even EDTA, since there was no problem of calcium phosphate precipitation.

Insufficient lubricant volume is another possible reason for the problematic protein slurry formation [19]. Since no such problem was encountered in the present tests, it can be deduced that 16 ml of the present lubricant, alpha calf serum diluted 1:1, is sufficient with a load of 70.7 N and sliding velocity of 31.4 mm/s, at least with the clinically most widely used combination, polyethylene against CoCr. The average wear factor,  $1.63 \times 10^{-6} \text{ mm}^3/\text{N m}$ , cannot be considered too low in relation to clinical findings [5]. The temperature control system of the Super-CTPOD allows the use of a wide range of temperatures. The minimum lubricant temperature that was achieved in system tests was 8 °C, as the cold tap water

temperature of the laboratory was 7 °C. On the other hand, temperatures above 40 °C proved problematic, as they led to excessive evaporation.

With the 12-station CTPOD, a test has been done so that the specimens and the test conditions in all 12 stations were similar to those of the present study [20]. The only differences were that the lubricant volume was 12 ml, and the average lubricant bulk temperature was 28 °C. The mean wear factor was found to be  $1.19 \times 10^{-6} \text{ mm}^3/\text{N m}$ , 27 % lower than that of the present study, and the SD was 9.2 % of the mean. It is logical to assume that the lower  $k$  value in the 12-station CTPOD test was due to the smaller lubricant volume and higher lubricant temperature, as the amount of precipitated protein involved in the wear mechanism was probably higher, resulting in a lower wear rate, in conformity with hip joint simulator studies [19,21].

The nominal contact pressure used, 1.1 MPa, is lower than the values used by my most other researchers. However, the average load value in a hip joint during a gait cycle being 1000 N [22], the average contact pressure value on the contact zone with this load is likely to be within the range 1–2 MPa. A simplified formula assuming hemispherical contact, ellipsoidal contact pressure distribution, and 28 mm head dia. yields  $0.785 \times 0.386 \times 1000/14^2 = 1.5 \text{ MPa}$  for the average pressure [23]. The average value is a sensible choice for a pin-on-disk device. Excessive pressure is likely to lead to abnormal thermal phenomena [18]. Overheating of the tribocontact is a pitfall to be avoided in wear testing. After all, a simulator must, for practical reasons, run 24 hours a day, which undeniably differs from the activity of a typical arthroplasty patient. The present results indicated that static loading is sufficient. Dynamic loading did not appear necessary, but it is a feature that can be added later.

The usefulness of the CTPOD principle is not limited to the study of soft materials against hard counterfaces. It has been shown to produce valid wear also for hard-on-hard couples [24]. With these, it is recommendable to use a ball-on-flat contact and very low loads.



## **CONCLUSIONS**

For the first time, the number of similar tests done for the widely used conventional UHMWPE was sufficiently large (100) for obtaining a 95 % confidence interval for the mean wear factor as low as  $\pm 1.1$  % of the mean value, and for proving that the wear factor is normally distributed. This was made possible by the low variation of results without a single outlier, which is indicative of a high-quality test method. The test conditions were shown to closely simulate the clinical conditions in the prosthetic hip joint. Moreover, the results indicated that in order to produce wear similar to that known to occur clinically the lubricant temperature of 20 °C is preferable to higher values due to factors related to protein degradation that is inevitable in vitro in contrast to in vivo conditions.

Altogether, the Super-CTPOD wear test system was shown to be a unique and superior combination of validity, low variation, capacity, efficiency, reliability, productivity, economy, ease of operation, and compact size, making it the most original and useful innovation among contemporary wear simulators for prosthetic joint materials. The Super-CTPOD is the solution to the capacity problem of valid wear simulation, and has true potential to mark a new epoch in the biotribology research of orthopaedic biomaterials.

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## FIGURE CAPTIONS

Figure 1. Super-CTPOD, 100-station hip wear simulator with multidirectional motion.

Figure 2. Super-CTPOD main modules (loading, motion, and pin guiding) shown separated. Test chambers filled with serum-based lubricant and surrounded by coolant water, installed in motion module. Pins attached with press-fit sleeves to pin guiding shafts.

Figure 3. One Super-CTPOD test chamber consisting of test disk, PVC brim and o-ring seal, and one test pin attached to guiding shaft with plastic sleeve. Flanges of shafts protect test chambers against contamination from above. Note diamond coating of ends of stainless steel shafts preventing crevice corrosion.

Figure 4. Tools for assembly and disassembly of specimens, their holders, and test chambers.

Figure 5. Polyethylene test pins on handling tray after 3 million cycles. Topographical features appear pronounced due to polishing. Reflection of light varies because pin height on this handling tray varies slightly.

Figure 6a,b. Optical micrographs from polyethylene surface worn for 3 million cycles.

Figure 7a,b. Scanning electron micrographs of polyethylene wear particles on polycarbonate filter with 0.05  $\mu\text{m}$  pore size.

Figure 8. Gravimetric wear (weight loss) of polyethylene pins. Each circle represents mean value of 100 pins. Vertical bars indicate standard deviation of weight loss since previous weighing.

Figure 9. Frequency histogram and relative cumulative frequency of wear factor  $k$ .

Figure 10. Normal probability plot of wear factor  $k$  ( $10^{-6} \text{ mm}^3/\text{N m}$ ) with regression line passing through the first and third quartiles, and 95 % confidence limits.

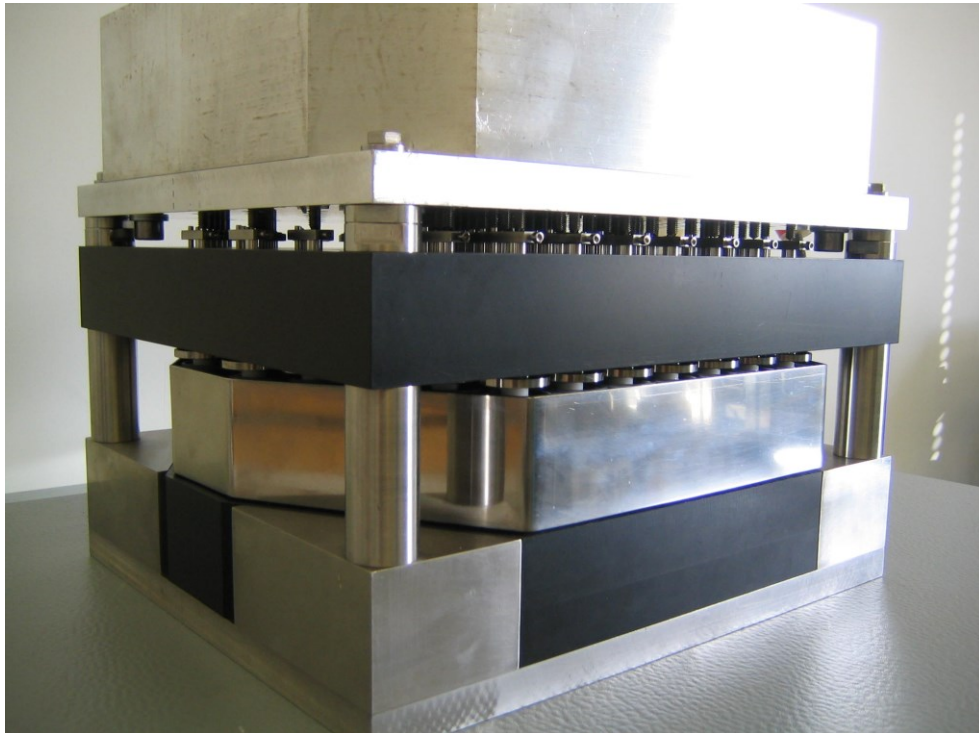


Figure 1.

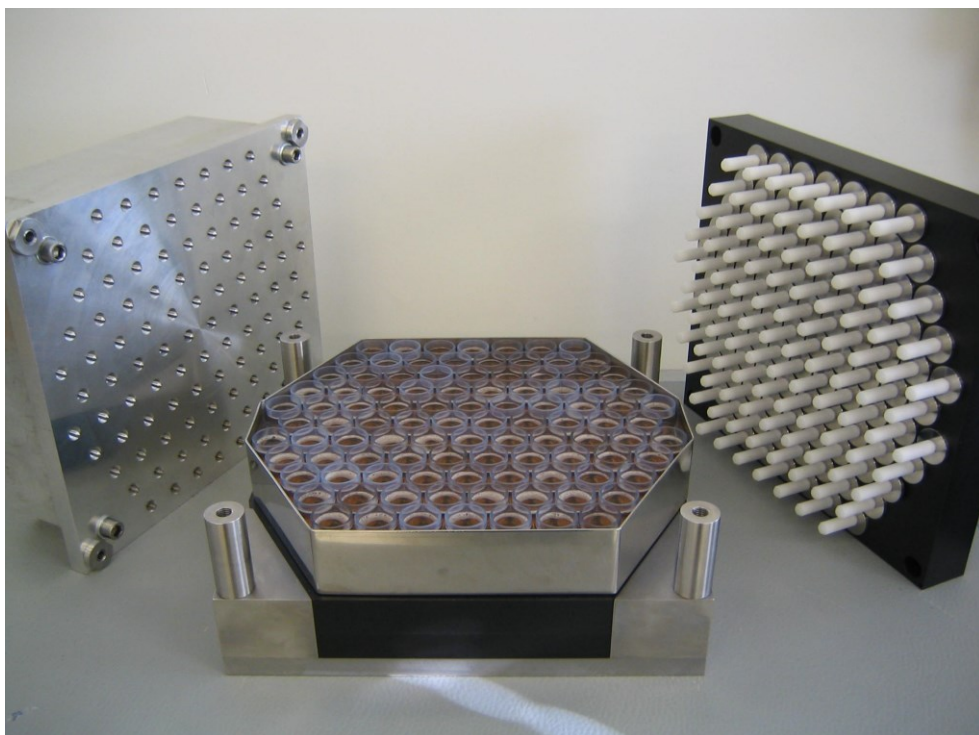


Figure 2.

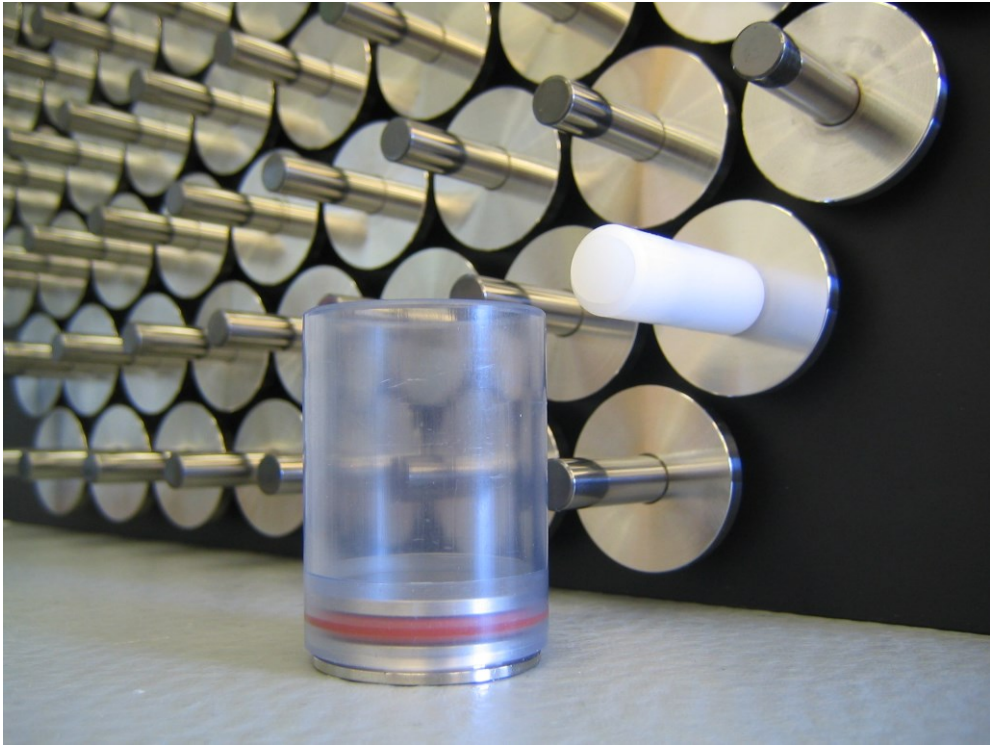


Figure 3.



Figure 4.





Figure 5.



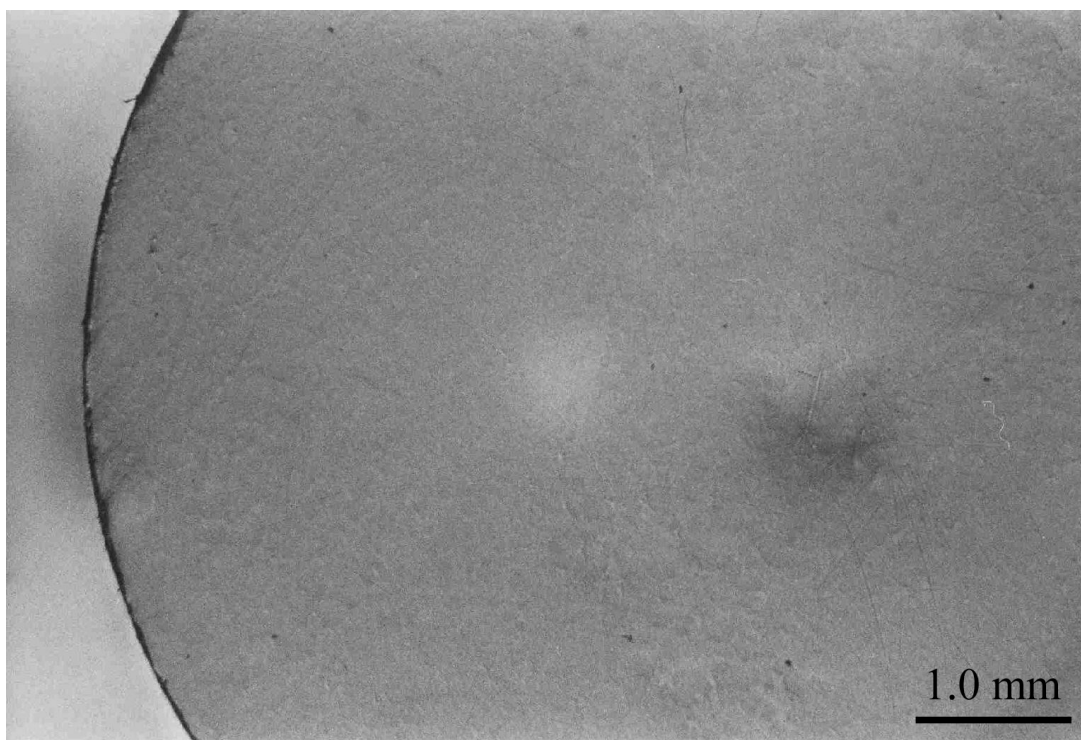


Figure 6a.

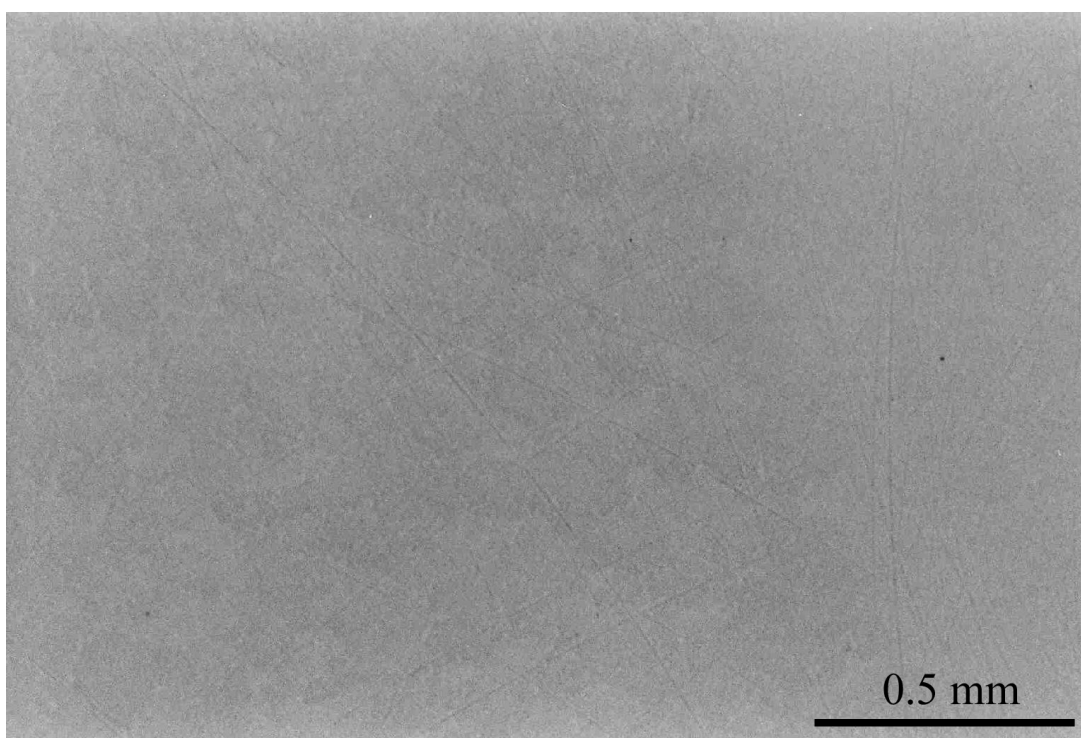


Figure 6b.

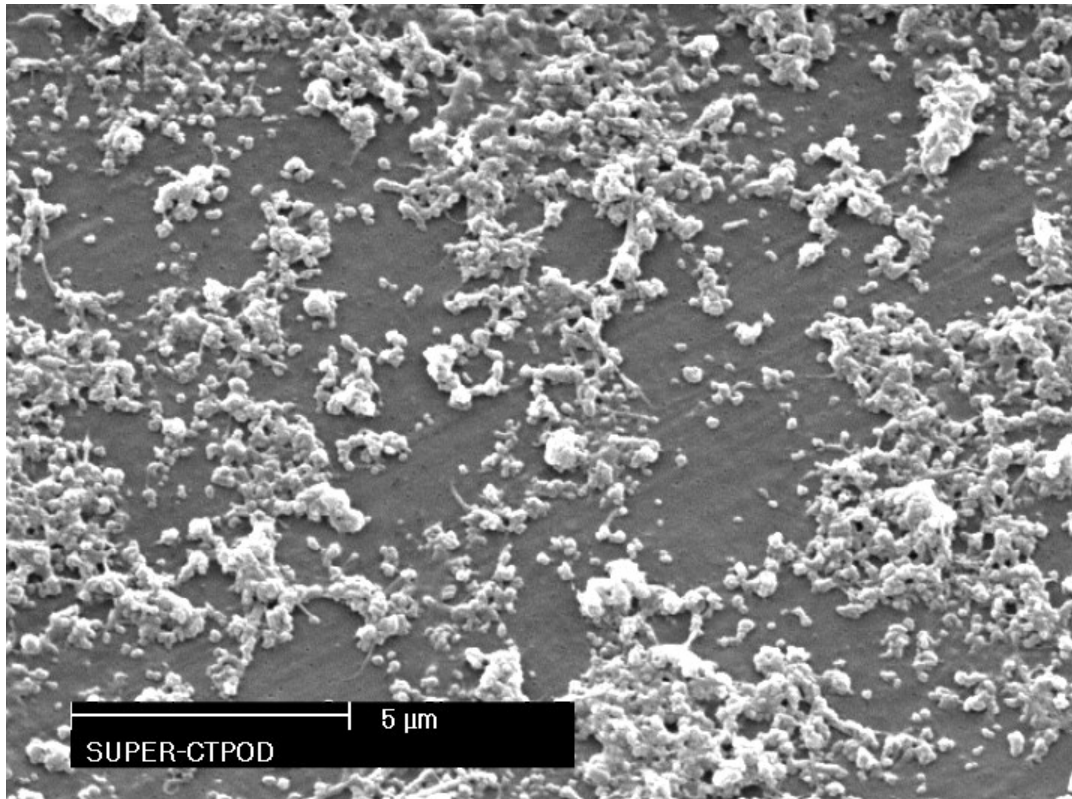


Figure 7a.

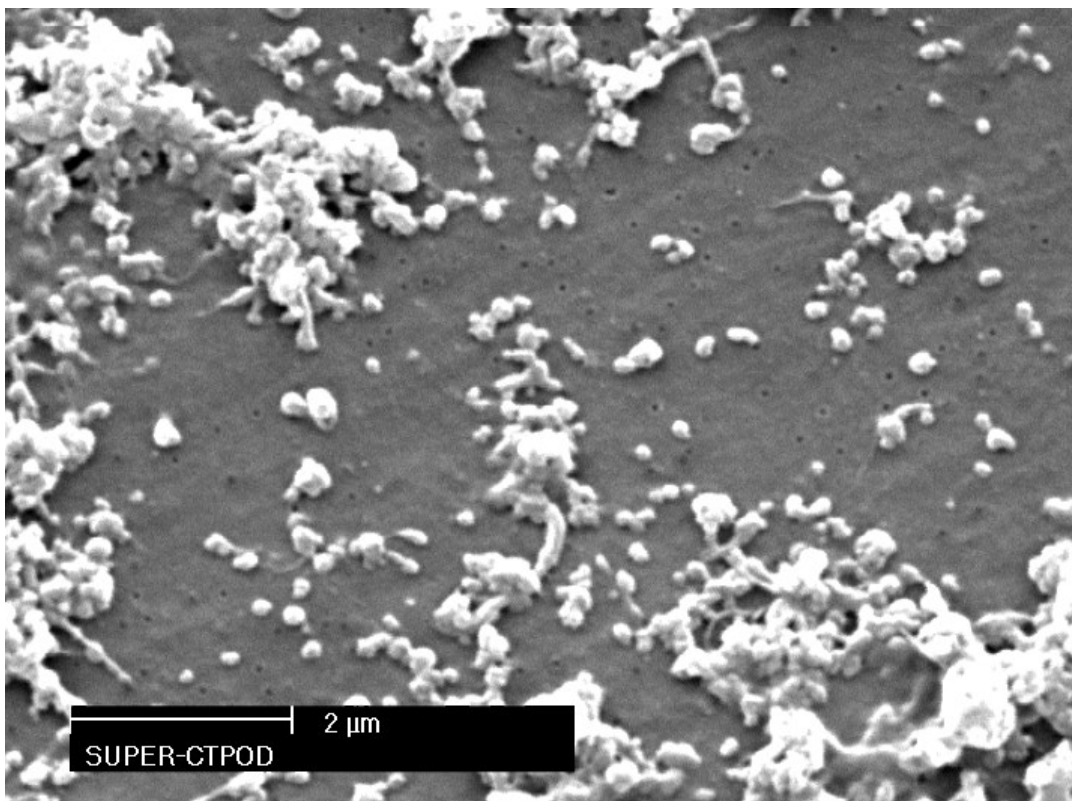


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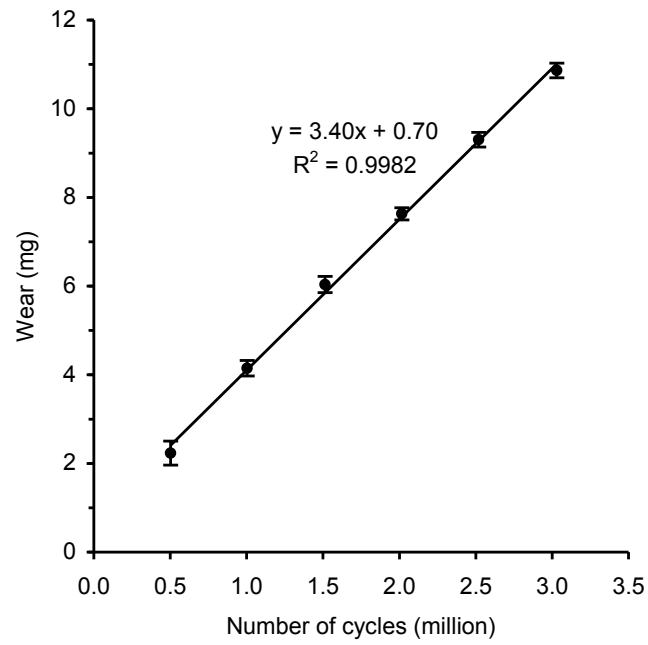


Figure 8.

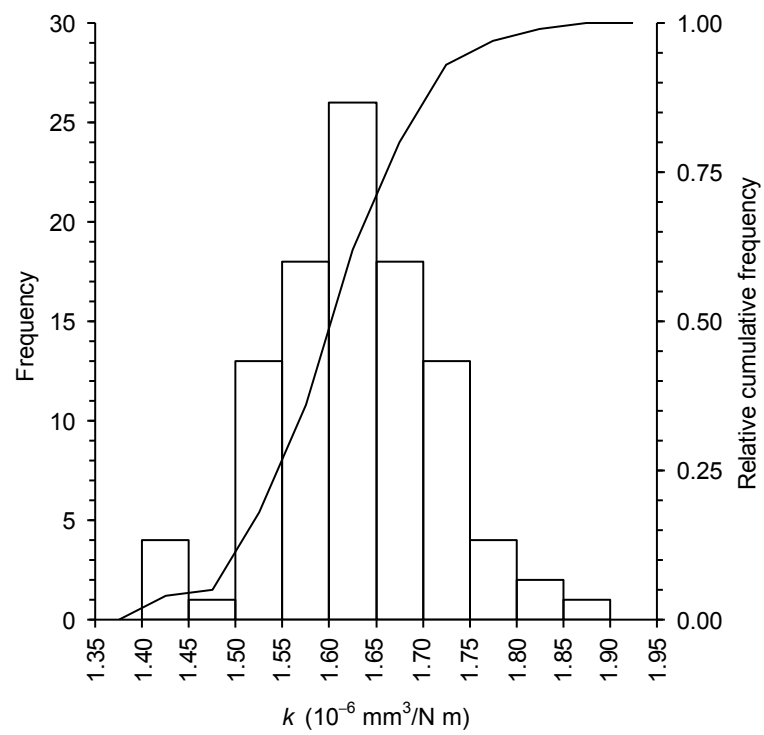


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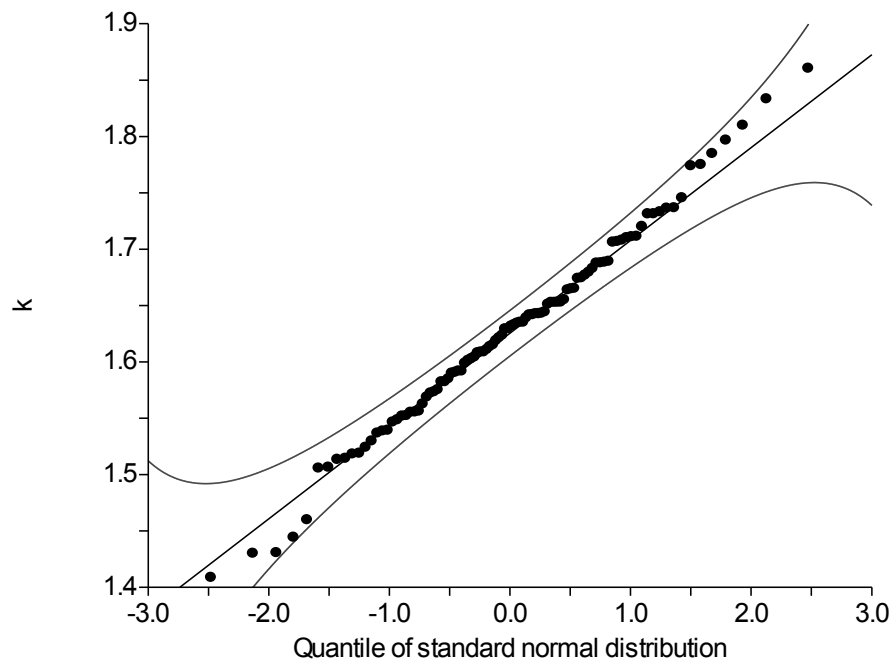


Figure 10.

Table 1. Contemporary multidirectional motion pin-on-disk devices for hip wear simulation.

Type of device	Motions	Number of test stations	Reference
Boston	two translations	1 with 6 specimens	[8]
Durham	one translation, one rotation	4	[9]
Winterthur	two rotations	4	[10]
Ortho-POD	two rotations	6	[11]
Leeds	one translation, one rotation	6	[12]
CTPOD	two translations	12	[1]
Super-CTPOD	two translations	100	Present study

Table 2. Descriptive statistics of wear factor  $k$  ( $10^{-6}$  mm<sup>3</sup>/N m) in Super-CTPOD test.

Statistic	Value
Mean $\pm$ 95 % confidence interval	1.63 $\pm$ 0.017
Sample variance	0.0077
Standard deviation	0.088
Minimum	1.41
First quartile (25th percentile)	1.57
Median	1.63
Third quartile (75th percentile)	1.68
Maximum	1.86
Sample size	100
Kurtosis	3.16
Skewness	0.05